

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8562

Bartle, C.J.

November 15, 2010

Terry Rossell ("Mr. Rossell" or "claimant") a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Virginia K. Rossell, Mr. Rossell's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated April 19, 2000,⁴ Dr. Johnson attested in Part II of Mr. Rossell's Green Form that claimant suffered from moderate aortic regurgitation and had

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Although Dr. Johnson reported in the Green Form that the date of claimant's echocardiogram was April 18, 2000, the echocardiogram report in the Show Cause Record reflects a "Service Date" of April 19, 2000. We need not resolve this discrepancy as neither the Trust nor claimant asserts that there are different echocardiograms at issue in this claim.

surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin and/or Redux.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$733,670.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, M. L. Gupta, M.D., stated that claimant had "at least moderate aortic stenosis." Dr. Johnson, however, attested in claimant's Green Form that Mr. Rossell did not suffer from aortic stenosis. Under the Settlement Agreement, the presence of aortic stenosis, which is defined as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation," requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)e). As the Trust does not contest Mr. Rossell's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

5. Dr. Johnson also attested that claimant suffered from mild mitral regurgitation, an abnormal left ventricular dimension, an abnormal left atrial dimension, a reduced ejection fraction in the range of 40% to 49%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin and/or Redux." See Settlement Agreement § IV.B.2.c.(3)(a).

In May, 2005, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists.⁷ In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant did not have aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation. In support of this conclusion, Dr. Irani explained that:

[Aortic valve] area calculation incorrect with gross overestimation of [left ventricular outflow tract] diameter by 50% thereby increasing the [aortic valve] area. [Left ventricular outflow tract] [velocity time integral] not traced on tape. Visually I would estimate [aortic valve] area at 0.8-0.9 cm². I personally clipped the images on my [echocardiogram] machine and performed a continuity equation calculation by tracing the Doppler envelopes in the [left ventricular outflow tract] and across the [aortic valve]. The calculated [aortic valve] area = 0.73 cm².

Based on Dr. Irani's findings, the Trust issued a post-audit determination that Mr. Rossell was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant

7. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that Mr. Rossell presented a Matrix A, Level III claim, the Trust audited Mr. Rossell's claim pursuant to the PPP.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after

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submitted a verified statement from Dr. Johnson, wherein he stated that:

In my opinion, to a reasonable degree of medical certainty, Mr. Rossell's aortic valve area was greater than 1.0 square centimeter by the Continuity Equation prior to his June 9, 2000 aortic valve replacement surgery.

I have measured the [left ventricular outflow tract] shown on the videotape of the echocardiogram and believe that 3.0 cm is the correct measurement.... When that figure is plugged into the Continuity Equation along with the other measurements on the videotape, the resulting aortic valve area is greater than 1.0 square centimeter.

In addition, claimant argued that there was a reasonable medical basis for Dr. Johnson's Green Form representation because a report of a cardiac catheterization performed five weeks later by a different cardiologist had an "almost identical" aortic valve measurement. Claimant also contended that he should prevail because the auditing cardiologist failed to "re-measure[]" the aortic valve area and instead relied on his "visual estimation," which claimant suggested was unreliable because Dr. Irani had difficulty viewing claimant's echocardiogram. Finally, claimant submitted a number of still frames in support of his claim.

The Trust then issued a final post-audit determination, again determining that Mr. Rossell was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final

8. (...continued)

December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Rossell's claim.

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Rossell's claim should be paid. On November 8, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5841 (Nov. 8, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 5, 2006, and claimant submitted a sur-reply on May 3, 2006. Under the Audit Rules it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

are now before the court for final determination. See id.
Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he did not have aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation. See id. Rule 24. Ultimately if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Rossell reasserts the arguments made in contest and argues that there is a reasonable medical basis for his claim because at least three physicians concluded that his aortic valve area was greater than 1.0 square centimeter. Claimant also relies on a report from Alan R. Maniet, D.O., F.A.A.I.M.¹⁰ In his report, Dr. Maniet stated that:

10. The Trust did not object to claimant's request to submit Dr. Maniet's report following contest, even though the Trust already had issued its final post-audit determination and applied to the court for issuance of an Order to show cause.

The m-mode echocardiogram displaying the aortic valve from the parasternal view shows the aortic valve to be clearly opening with a measurement of 1.1 cm. In addition the two-dimensional views in the parasternal short axis again clearly show opening of the aortic valve. The left ventricular outflow tract dimension measured from the parasternal long axis view was 2.62cm illustrating an enlarged dimension. This was further corroborated by the fact that a 25mm valve was inserted during surgery. The cardiac catheterization findings, pathologic reports illustrating three thickened leaflets removed at the time of surgery and this echocardiogram all appear to be consistent with an aortic valve area of greater than 1.0 cm².

In specific reference to the auditor's opinion that the [left ventricular outflow tract] dimension was grossly over measured, this is not supported by echocardiogram measurements. In addition since [there] was significant aortic regurgitation present the degree of aortic stenosis can be easily overestimated utilizing the standard calculations such as the continuity equation which is probably why there are questions in this case, a point which is well documented in the medical literature.

In response, the Trust argues that the reviewing cardiologist did not appear to have used the Continuity Equation. According to the Trust, even if Dr. Gupta did use the Continuity Equation, the "[left ventricular outflow tract] diameter measurements on the tape were grossly inflated and led to an exaggerated atrial area measurement." The Trust also argues that claimant's reliance on the report of his cardiac catheterization is misplaced because the Continuity Equation cannot be performed using a cardiac catheterization. In addition, although not required to do so, the Trust forwarded the claim for a second

review by the auditing cardiologist. Dr. Irani reviewed the additional materials submitted by claimant and prepared a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation. Specifically, Dr. Irani stated that:

While there are correlations between the size of the aortic root and the size of the prosthetic valve and between the diameter of the native aortic valve and the diameter of the prosthetic valve, there is no direct correlation between the size of the valve opening on Mr. Rossell's native valve at the time of the echo, and the size of the prosthetic valve.

(emphasis in original). Dr. Irani also opined that "[t]he manner in which the leaflets were removed sheds no light on the size of Mr. Rossell's aortic valve opening." Finally, Dr. Irani determined that "Dr. Maniet incorrectly applied the Continuity Equation in reaching his conclusion that Mr. Rossell does not have aortic stenosis with an aortic valve area $< 1.0 \text{ cm}^2$."

According to Dr. Irani:

Dr. Maniet improperly relied upon an incorrect measurement of the radius of the [left ventricular outflow tract]. The measurement of the [left ventricular outflow tract] diameter at 3.01 cm was obtained from a particularly unclear frame on Mr. Rossell's echocardiogram tape, notwithstanding the availability of better views of the left ventricular outflow tract in other frames. Dr. Maniet's remeasurement of 2.62 cm was also inflated and, when used in the Continuity Equation, served to significantly

exaggerate the measurement of Mr. Rossell's actual aortic area.

(emphasis in original). Finally, Dr. Irani explained that:

I measured the diameter of the left ventricular outflow tract at three different points on the echocardiogram tape (1.90 cm, 1.92 cm, and 2.31 cm) - all of which were clearer than the view measured on Claimant's tape. I determined that the average of these measurements is 2.05 cm, with the largest of the three measurements at 2.3 cm.

Accordingly, I reaffirm my finding that Claimant has aortic stenosis with an aortic valve area [of] 0.84 cm² by the Continuity Equation and that there is no reasonable medical basis for the Attesting Physician's representation that Claimant does not have aortic stenosis with an aortic valve area < 1.0 cm² by the Continuity Equation.

In his sur-reply, claimant argues that the issue before the court is whether there is a reasonable medical basis for his attesting physician's finding regarding aortic stenosis, and "is not a matter of right or wrong." In support, claimant submits a supplemental report from Dr. Maniet. In his supplemental report, Dr. Maniet confirmed his previous finding that claimant's aortic valve opening was greater than 1.0 square centimeter. Specifically, Dr. Maniet stated: "I stand by my original opinion that my measurements are accurate and not grossly exaggerated since they were confirmed at the time of surgery." Finally, Dr. Maniet noted that "[t]he fact that the faulty valve was taken out in three pieces" supported a finding that claimant's aortic valve area was greater than 1.0 square centimeter when viewed in the context of the pathology report and echocardiogram.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Rossell did not have aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. Specifically, Dr. Vigilante concluded:

There were marked abnormalities of the aortic valve with severe calcification and significant restriction of aortic leaflet motion consistent with aortic stenosis. I made multiple measurements independently. The left ventricular outflow tract diameter averaged at 2.28 cm. The calculation of the left ventricular outflow tract diameter on the echocardiogram tape by the sonographer is incorrect and clearly excessive. Several tracings of the pulse wave doppler of the left ventricular outflow tract flow as well as continuous wave doppler of the aortic valve flow were obtained and digitized. Five cardiac cycles were averaged. The mean gradient across the aortic valve was calculated at 48 mmHg. The aortic valve area was determined to be 0.75 cm squared. This was in association with moderate aortic insufficiency. It should be noted that the presence of aortic insufficiency does not significantly change the aortic valve area as determined by the Continuity Equation as both velocities in the left ventricular outflow tract as well as stenosed aortic valve will be increased with [aortic insufficiency]. In addition, these results correlate well with those of the cardiac surgeon who found a severely stenotic aortic valve at the time of surgery.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor applied an inappropriate standard of review. Claimant also suggests that the Continuity Equation is not the best method for measuring aortic stenosis.

In addition, claimant contends that inter-reader variability can account for the differences in the measurements of Mr. Rossell's left ventricular outflow tract. Finally, claimant asserts that the Technical Advisor did not consider all of the evidence indicating that Mr. Rossell did not have an aortic valve area of less than 1.0 square centimeter, including the fact that claimant had a 25 mm valve inserted during valve replacement surgery.

After reviewing the entire show cause record, we find claimant has failed to meet his burden of demonstrating that he is entitled to Matrix A-1 benefits. The Settlement Agreement requires that a claim for benefits based on damage to the aortic valve be reduced to Matrix B-1 if claimant had aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. See Settlement Agreement § IV.B.2.d.(2)(c)i)e).¹¹ Here, the auditing cardiologist and the Technical Advisor found that claimant's aortic valve area was less than 1.0 square centimeter. Specifically, Dr. Irani concluded that Mr. Rossell's "aortic valve area was 0.84 cm² by the Continuity Equation"¹² Dr. Vigilante similarly stated that Mr. Rossell's "aortic valve area was determined to be 0.75

11. We reject claimant's argument that he may disprove the existence of aortic stenosis by a method other than the Continuity Equation, which is specifically required by the Settlement Agreement. See Settlement Agreement § IV.B.2.d.(2)(c)i)e).

12. As Dr. Irani subsequently provided measurements of the left ventricular outflow tract and aortic valve area, we need not address claimant's argument that visual estimation is improper.

cm squared" and that "[a]n echocardiographer could not reasonably conclude that aortic stenosis with a valve area of less than 1.0 cm squared was not present on this echocardiogram."¹³

We also reject claimant's argument that the opinions of Dr. Johnson and Dr. Maniet provide a reasonable medical basis for his claim. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include, among other things, overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 15, 21-22 (Nov. 14, 2002). Similarly, overtracing a claimant's left ventricular outflow tract is improper. Dr. Irani determined that "Dr. Maniet improperly relied upon an incorrect measurement of the radius of the [left ventricular outflow tract]." Dr. Irani also opined that "Dr. Maniet's remeasurement of 2.62 cm was also inflated and, when used in the Continuity Equation, served to significantly exaggerate the measurement of Mr. Rossell's actual aortic area." (emphasis in original). Dr. Vigilante likewise observed that both Dr. Johnson and Dr. Maniet relied upon improper measurements because "[t]he calculation of the left ventricular outflow tract diameter on the echocardiogram tape by the sonographer is incorrect and clearly excessive." Such unacceptable measurements cannot provide a reasonable medical basis for the resulting

13. For this reason as well, we disagree with claimant that the size of his replacement valve and the manner in which the leaflets were removed during surgery support the conclusion that his aortic valve area was greater than 1.0 square centimeter.

diagnosis and Green Form representation that claimant did not have aortic stenosis.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation regarding Mr. Rossell's aortic stenosis is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. Adopting claimant's argument on inter-reader variability would allow a claimant to recover Matrix A benefits when he or she suffered from aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. This result would render meaningless this critical provision of the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he did not have aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation. Therefore, we will affirm the Trust's denial of Mr. Rossell's claim for Matrix A benefits and the related derivative claim submitted by his spouse.